

# EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

BAVARIAN NORDIC A/S,	)	
	)	
Plaintiff/	)	
Counterclaim Defendant,	)	
	)	C.A. No. 05-614 (SLR)
v.	)	
	)	<b>FILED UNDER SEAL</b>
ACAMBIS INC. and	)	
ACAMBIS PLC,	)	
	)	
Defendants/	)	
Counterclaim Plaintiffs.	)	
_____	)	

**DEFENDANTS' AMENDED ANSWER AND COUNTERCLAIMS**

Defendants Acambis Inc. and Acambis, plc (collectively "Defendants" or "Acambis"), hereby answer and otherwise respond to the Complaint of Bavarian Nordic A/S ("Plaintiff" or "BN") and assert counterclaims against BN as follows:

**FIRST DEFENSE – FED. R. CIV. P. 8(b)**

**NATURE OF CASE**

1. Defendants deny that they have committed any acts of unfair competition, conversion, or misappropriation of trade secrets in violation of the laws of the United States or the State of Delaware. Defendants further deny that BN is entitled to any relief on any of the claims set forth in the Complaint.

**JURISDICTION**

2. Defendants admit that this action is between parties whose citizenship is diverse and that BN seeks relief in excess of \$75,000. Defendants further admit that BN cites the Lanham Act as providing federal question subject matter jurisdiction under 28 U.S.C. § 1338.

Defendants deny the remaining allegations set forth in Paragraph 2 of the Complaint insofar as they constitute legal conclusions to which no response is required.

3. Defendants admit that this Court has personal jurisdiction in this matter and that venue lies in this District. Defendants deny the remaining allegations set forth in Paragraph 3 of the Complaint insofar as they constitute legal conclusions to which no response is required.

#### **THE PARTIES**

4. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 4 of the Complaint and therefore deny those allegations. Defendants further deny that BN owns any proprietary information or material upon which a claim may be based against Acambis.

5. Defendants deny that the acts complained of in the Complaint occurred in Delaware. Defendants admit the remaining allegations set forth in Paragraph 5 of the Complaint.

6. Defendants deny that the acts complained of in the Complaint occurred in Delaware. Defendants admit the remaining allegations set forth in Paragraph 6 of the Complaint.

7. Defendants deny the allegations set forth in Paragraph 7 of the Complaint insofar as they constitute legal conclusions to which no response is required. Defendants admit that Acambis Inc. and Acambis plc share research personnel and jointly market vaccine product to the U.S. Government.

#### **FACTUAL BACKGROUND**

8. Defendants admit that the allegations set forth in Paragraph 8 of the Complaint are generally correct.

9. Defendants admit that the allegations set forth in Paragraph 9 of the Complaint are generally correct, and affirmatively aver that other smallpox vaccines – including some that

are derived from the Dryvax® virus strain and some that are derived from other virus strains – are being currently evaluated.

10. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 10 of the Complaint and therefore deny those allegations.

11. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 11 of the Complaint and therefore deny those allegations.

12. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 12 of the Complaint and therefore deny those allegations.

13. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 13 of the Complaint and therefore deny those allegations.

14. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 14 of the Complaint and therefore deny those allegations. Defendants affirmatively aver that in an action filed contemporaneous with this suit before the U.S. International Trade Commission (“TTC action”), BN has accused Defendants of infringing the patents identified in Paragraph 14. In that forum, Defendants have challenged the alleged infringement, validity, and enforceability of the patents.

15. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 15 of the Complaint and therefore deny those allegations.

16. Defendants admit the allegations set forth in Paragraph 16 of the Complaint.

17. Defendants deny providing ACAM2000 vaccine under the contract awarded in September 2000. Defendants admit the remainder of the allegations set forth in Paragraph 17 of the Complaint. Defendants affirmatively aver that Acambis received a competitively awarded contract from the U.S. Government in September 2000 to research, develop and license a

smallpox vaccine derived from the same vaccine strain as Dryvax® (ACAM1000), and that Acambis received a second competitively awarded U.S. Government contract in November 2001 to research, develop, manufacture and license a smallpox vaccine derived from the same vaccine strain as Dryvax® (ACAM2000).

18. Defendants deny the allegations set forth in Paragraph 18 of the Complaint.

19. Defendants admit that Baxter Healthcare SA ("Baxter") is Acambis Inc.'s subcontract manufacturer of MVA3000 under two prime contracts between the U.S. Government and Acambis Inc. Defendant further admits that Baxter manufactures or intends to manufacture MVA3000 in Europe, at least in substantial part, for delivery in the United States to the U.S. Government. Defendant denies the remainder of the allegations in Paragraph 19 of the Complaint. Defendants also affirmatively aver that their only current MVA3000 "customer" in the United States is the U.S. Government.

20. Defendants deny the allegations set forth in Paragraph 20 of the Complaint. Defendants further deny the allegations set forth in Paragraph 20 of the Complaint insofar as they constitute legal conclusions to which no response is required.

21. Defendants deny the allegations set forth in Paragraph 21 of the Complaint. Defendants further deny the allegations set forth in Paragraph 21 of the Complaint insofar as they constitute legal conclusions to which no response is required.

22. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 22 of the Complaint and therefore deny those allegations.

23. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 23 of the Complaint and therefore deny those allegations.

Defendants deny that BN holds an exclusive license for the commercialization of all Modified Vaccinia Ankara (“MVA”) strains.

24. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 24 of the Complaint and therefore deny those allegations.

25. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 25 of the Complaint and therefore deny those allegations.

26. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 26 of the Complaint and therefore deny those allegations.

27. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 27 of the Complaint and therefore deny those allegations.

28. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 28 of the Complaint and therefore deny those allegations. Defendants deny that they were under any restriction with respect to the use of any MVA strain provided to them by the NIH.

29. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 29 of the Complaint and therefore deny those allegations.

30. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 30 of the Complaint and therefore deny those allegations.

31. Defendants admit that Acambis plc entered into an agreement entitled “Secrecy Agreement” with BN in February 2002, but deny the remaining allegations set forth in Paragraph 31.

32. Defendants admit that personnel from Acambis and BN met at Acambis’ offices in Cambridge, Massachusetts, on June 12, 2002, and that Thomas Monath, the Chief Scientific

Officer of Acambis Inc., attended some or all of the meeting. Defendants are without knowledge sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 32 and therefore deny those allegations. Defendants further deny that BN disclosed any non-public, confidential or proprietary information during that meeting, or that Defendants misappropriated any such information for their own commercial benefit.

33. Defendants admit that sometime in 2002, BN delivered a draft outline of a proposal for a potential collaboration between BN and Acambis. Defendants deny the remaining allegations set forth in Paragraph 33.

34. Defendants admit that the allegations set forth in Paragraph 34 of the Complaint are generally correct, but affirmatively aver that the U.S. Government expressed an interest in stockpiling smallpox vaccines prior to September 11, 2001, and acted on that interest by competitively awarding Acambis a smallpox vaccine contract in September 2000 (ACAM1000).

35. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 35 of the Complaint and therefore deny those allegations. Defendants admit that personnel from Acambis and BN met at Acambis' offices in Cambridge, Massachusetts, on June 12, 2002, but affirmatively aver that neither NIAID nor NIH were present at, nor participated in, that meeting.

36. Defendants admit that NIAID NIH released the First RFP in September 2002 outlining the requirements for an attenuated form of the smallpox vaccine virus, including dosage. Defendants deny the remaining allegations in Paragraph 36 of the Complaint. Defendants affirmatively aver that the First RFP invited any offeror to enter into "collaborative opportunities" with the NIH and that such opportunities were specifically not part of the RFP. These "opportunities" included "the availability of master seed stock of MVA from NIAID."

37. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 37 of the Complaint and therefore deny those allegations.

38. Defendants admit the allegations set forth in Paragraph 38 of the Complaint.

39. Defendants admit receiving MVA Virus 572.FHE-22.02.1974, which was plaque purified by Dr. Bernard Moss, from NIH NIAID. Defendants deny the remainder of the allegations in Paragraph 39. Defendants affirmatively aver being in possession of MVA vaccine strains prior to the contract award in February 2003.

40. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 40 of the Complaint and therefore deny those allegations.

41. Defendants admit that they initiated human clinical trials of MVA3000 under a U.S. Investigational New Drug (IND) application in 2004 and announced results of those trials in April 2005. Defendants deny the remaining allegations set forth in Paragraph 41 of the Complaint.

42. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 42 of the Complaint and therefore deny those allegations. Defendants deny that BN disclosed any non-public, confidential or proprietary information to Defendants, or that Defendants misappropriated any such information for their own commercial benefit.

43. Defendants deny the allegations set forth in Paragraph 43 of the Complaint.

#### **COUNT I – TORTIOUS CONVERSION**

44. Defendants incorporate Paragraphs 1 through 43 above by reference.

45. Defendants deny the allegations set forth in Paragraph 45 of the Complaint.

46. Defendants deny the allegations set forth in Paragraph 46 of the Complaint.



47. Defendants deny the allegations set forth in Paragraph 47 of the Complaint.

48. Defendants deny the allegations set forth in Paragraph 48 of the Complaint.

49. Defendants deny the allegations set forth in Paragraph 49 of the Complaint.

50. Defendants deny the allegations set forth in Paragraph 50 of the Complaint.

**COUNT II – MISAPPROPRIATION OF TRADE SECRETS**

51. Defendants incorporate Paragraphs 1 through 50 above by reference.

52. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 52 of the Complaint and therefore deny those allegations. Defendants deny that BN disclosed any non-public, confidential or proprietary information to Defendants, or that Defendants misappropriated any such information for their own commercial benefit.

53. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 53 of the Complaint and therefore deny those allegations. Defendants deny that BN disclosed any non-public, confidential or proprietary information to Defendants, or that Defendants misappropriated any such information for their own commercial benefit.

54. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 54 of the Complaint and therefore deny those allegations. Defendants deny that BN disclosed any non-public, confidential or proprietary information to Defendants, or that Defendants misappropriated any such information for their own commercial benefit.

55. Defendants deny the allegations set forth in Paragraph 55 of the Complaint.

56. Defendants admit that, as of June 12, 2002, they were aware that BN was seeking to develop a MVA-based smallpox vaccine. Defendants deny the remaining allegations set forth in Paragraph 56 of the Complaint.

57. Defendants deny the allegations set forth in Paragraph 57 of the Complaint.

58. Defendants deny the allegations set forth in Paragraph 58 of the Complaint.

59. Defendants deny the allegations set forth in Paragraph 59 of the Complaint.

60. Defendants deny the allegations set forth in Paragraph 60 of the Complaint.

61. Defendants deny the allegations set forth in Paragraph 61 of the Complaint.

### **COUNT III – UNFAIR TRADE PRACTICES**

62. Defendants incorporate Paragraphs 1 through 61 above by reference.

63. Defendants deny the allegations set forth in Paragraph 63 of the Complaint.

64. Defendants deny the allegations set forth in Paragraph 64 of the Complaint.

65. Defendants deny the allegations set forth in Paragraph 65 of the Complaint.

66. Defendants deny the allegations set forth in Paragraph 66 of the Complaint.

### **COUNT IV – LANHAM ACT UNFAIR COMPETITION**

67. Defendants incorporate Paragraphs 1 through 66 above by reference.

68. Defendants deny the allegations set forth in Paragraph 68 of the Complaint.

69. Defendants deny the allegations set forth in Paragraph 69 of the Complaint.

### **PRAYER FOR RELIEF**

Defendants deny that BN is entitled to any relief in this matter.

### **SECOND DEFENSE – FED. R. CIV. P. 8(c)**

a. BN brings this action with unclean hands by using the processes of this Court for improper business purposes.

b. BN's claims are barred by the doctrine of laches, estoppel, and/or waiver insofar as BN was aware of the alleged basis for the claims made in the Complaint at least as early as February 2003 – prior to the U.S. Government's subsequent MVA-related RFPs – but took no action. Such delay has caused and/or will cause prejudice and injury to Defendants and third parties.

c. Some or all of BN's claims may be subject to binding arbitration. For instance, BN's misappropriation of trade secrets claim and all related claims are subject to mandatory, binding arbitration pursuant to a February 2002 agreement between BN and Acambis. Pursuant to that Agreement, "All disputes and differences of any kind related to this Agreement...shall be finally settled under the Rules of the International Chamber of Commerce (the 'ICC') by one arbitrator appointed in accordance with said Rules." Based on that provision, on April 14, 2006, the ITC ALJ issued an Order terminating BN's trade secrets claim – which is coterminous with the trade secrets claim in this case – from the ITC action based on the above-referenced arbitration agreement. On May 9, 2006, the ITC determined not to review the ALJ's Order, which is now final.

d. BN's claims are barred insofar as BN and/or its agents provided the property and/or information at issue to the U.S. Government without restriction.

e. BN's claims are barred insofar as BN and/or its agents did not have the authority to restrict the U.S. Government's use and provision of the property and/or information at issue.

f. BN's claims are subject to the doctrine of inequitable conduct before the U.S. Patent and Trademark Office insofar as the claims are based on BN's alleged patent rights. BN's inequitable conduct is set forth in the counterclaims below and hereby incorporated by reference.

**THIRD DEFENSE – FED. R. CIV. P. 12(b)(6)**

BN fails to state any claim upon which relief can be granted under any theory.

**FOURTH DEFENSE – FED. R. CIV. P. 12(b)(7)**

BN's claims must be dismissed for failure to join the U.S. Government as an indispensable party insofar as the U.S. Government owns or will own the vaccines sought by BN's request for injunctive relief. That request includes a demand for the "return of all MVA virus and its progeny in the possession of [Defendants] and/or [their] suppliers." Prayer for Relief at ¶ D. The U.S. Government is also an indispensable party insofar as it is alleged in the Complaint (*see, e.g.*, ¶ 39) to be Defendants' supplier of the MVA strain used to develop and manufacture Defendants' MVA3000 vaccine. The proper forum for pursuing relief against the U.S. Government is the U.S. Court of Federal Claims pursuant to 19 U.S.C. § 1337(l) and/or the Tucker Act, 28 U.S.C. § 1491 *et seq.*

**FIFTH DEFENSE – FED. R. CIV. P. 12(e)**

BN's claim for trade secret violations under Delaware law fails for lack of specificity.

**SIXTH DEFENSE**

Pursuant to 28 U.S.C. § 1659, this action must be stayed pending a final determination of BN's ITC action to the extent that BN's claims in this case involve the same issues involved in the ITC action, which allege patent infringement and trade secret violations. In fact, all of the allegations set forth in the "Factual Background" of the Complaint in this case are taken almost *verbatim* from the factual allegations set forth in BN's ITC complaint. As set forth above, BN's trade secrets allegations were terminated from the ITC proceeding based on a mandatory arbitration agreement between the parties. A six-day evidentiary hearing before the ALJ in the ITC action on BN's patent infringement claims – the only claims remaining in the ITC action –

began on May 8. Following post-trial briefing by the parties to that action, the ALJ is scheduled to issue an initial determination by August 24, 2006. The ITC is scheduled to issue a final determination in that action by November 24, 2006.

#### **SEVENTH DEFENSE**

Defendants reserve the right to present additional affirmative defenses and/or responses and/or counterclaims as such matters are revealed during the course of the litigation.

#### **ACAMBIS' COUNTERCLAIMS**

##### **INTRODUCTION**

1. This is an action based on BN's illegal efforts to monopolize the market for MVA-based smallpox vaccines and prevent Acambis from selling its MVA-based smallpox vaccine to the U.S. Government. BN has sought to effectuate its illegal scheme through meritless litigation against Acambis in the U.S. International Trade Commission ("ITC") and in this Court based on fraudulently procured and clearly invalid patents and other unsupported theories. Through such litigation and other illegal conduct, BN has, among other things, threatened to interfere with Acambis' ability to bid on, procure, and fulfill contracts offered by the U.S. Government, artificially decreased the value of Acambis stock, damaged Acambis' reputation and good will, and cost Acambis millions of dollars in litigation fees and costs. Through this action, Acambis seeks a declaratory judgment of invalidity and unenforceability of BN's patents and recompense for the damage caused by BN's illegal conduct.

##### **THE PARTIES**

2. Counterclaim Plaintiff Acambis Inc. is a corporation duly organized and existing under the law of the State of Delaware, with a registered address of Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware, in the County of New Castle. Acambis Inc. is

headquartered at 38 Sidney Street, Cambridge, Massachusetts. Acambis Inc. is a wholly-owned subsidiary of counterclaim Plaintiff Acambis plc. (Counterclaim Plaintiffs, Acambis Inc. and Acambis plc, are collectively referred to herein as “Acambis.”) Acambis is a leading developer of vaccines against infectious diseases. As a fully-integrated biotechnology company, Acambis is capable of developing new vaccines from early-stage research through a final government-approved product.

3. Upon information and belief, as alleged in paragraph 4 of the Complaint, counterclaim Defendant Bavarian Nordic A/S (“BN”) is a corporation duly organized and existing under the laws of the nation of Denmark, and maintains its principal place of business at Bøgeskovvej 9, DK-3490 Kvistgård, Denmark.

## **REDACTED**

As set forth below, BN and Acambis have competed and continue to compete in the sale of certain smallpox vaccines to the U.S. Government.

### **JURISDICTION AND VENUE**

4. This Court has jurisdiction over the counterclaims for declaratory judgment based on an actual controversy between BN and Acambis arising under the United States Patent Laws, Title 35 of the U.S. Code, pursuant to 28 U.S.C. §§ 2201 *et seq.*, 1331, 1338(a) and 1367, and venue is proper in this Judicial District under 28 U.S.C. § 1391. This Court has jurisdiction over the antitrust counterclaims in this action pursuant to 15 U.S.C. §§ 2, 15 and 26, and 28 U.S.C. §§ 1331 and 1337, and venue is proper in this Judicial District under 15 U.S.C. §§ 15 and 22, and 28 U.S.C. § 1391. This Court has jurisdiction over the counterclaim for tortious interference with

valid contracts, business relations, and business expectancies pursuant to 28 U.S.C. §§ 1367 and 1332, and venue is proper in this Judicial District under 28 U.S.C. § 1391. This Court has jurisdiction over the counterclaim for false advertising under the Lanham Act pursuant to 15 U.S.C. §§ 1121 and 1125, and 28 U.S.C. §§ 1331 and 1338(b), and venue is proper under 28 U.S.C. § 1391. This Court has jurisdiction over the counterclaim for Delaware Deceptive Trade Practices and unfair competition pursuant to 28 U.S.C. §§ 1367 and 1332, and venue is proper in this Judicial District under 28 U.S.C. § 1391. Jurisdiction and venue are further established by the filing of this action against Acambis in this Judicial District.

### **BACKGROUND**

#### **Smallpox and Smallpox Vaccines**

5. Smallpox is an acute contagious disease caused by the variola virus. It is considered to be one of the deadliest infectious diseases in the history of humankind; it is estimated that more people have died of smallpox than from all other infectious diseases combined. Smallpox is usually spread from person to person through close contact, including face-to-face contact, contact with contaminated body fluids or objects, or by the air in enclosed spaces. Early symptoms of smallpox are a high fever, head and body aches, and vomiting. A rash follows that spreads and progresses to pus-filled blisters that crust, scab, and fall off after three weeks. One form of the disease, variola major, is highly virulent with a mortality rate of greater than 30 percent and a high rate of disfigurement in individuals that recover from the disease.

6. While there is no specific treatment or cure for smallpox, it can be prevented through vaccines. In fact, routine vaccination led to global eradication of the disease in 1979.

After eradication, routine vaccination was discontinued because the risks of vaccination outweighed the threat of disease.

7. The only smallpox vaccine currently approved by the U.S. Food and Drug Administration (“FDA”) for inoculating the general population in the United States is Dryvax®, which is a live-virus preparation of vaccinia virus prepared from calf lymph. While safe and effective for the vast majority of the population, the use of vaccines such as Dryvax® may result in serious side effects, particularly with immune-compromised individuals and individuals with certain skin conditions. In addition, because of the risk of spreading live vaccinia through the womb or breast milk, Dryvax® cannot be used with pregnant or lactating women. It is estimated that approximately 30 million U.S. citizens are not recommended for vaccination with Dryvax® or Dryvax®-based smallpox vaccines.

8. Other smallpox vaccines are currently being evaluated in clinical investigations. For example, Acambis was awarded a contract with the U.S. Government in September 2000 to research, develop, and manufacture a Dryvax®-based smallpox vaccine (“ACAM1000”). In November 2001, Acambis was awarded a second contract under which it developed and manufactured 182.5 million doses of a second Dryvax®-based smallpox vaccine (“ACAM2000”). Acambis’ Biologics License Application (“BLA”) for ACAM2000 is currently under review at the U.S. Food and Drug Administration.

#### **MVA-based Smallpox Vaccines**

9. Professor Anton Mayr developed a modified vaccinia Ankara (“MVA”) virus in the 1970s as an attenuated form of the chorioallantois vaccinia Ankara (“CVA”) smallpox virus for use as a vaccine in humans and other mammals. An attenuated virus is not able to spread



throughout the body, but can still enable a host mammal to develop immunity to the actual disease-causing smallpox virus, either as a pre-vaccine or as a stand-alone vaccine.

10. Professor Mayr developed MVA through a process of plaque purifying and passaging the virus in chicken embryo fibroblast (“CEF”) cells. Plaque purification is a process by which a specific viral particle is selected from a well of viral particles. The purpose of plaque purification is to homogenize a viral mixture. Passaging is a process of amplifying, or growing, larger stocks of a selected viral particle without changing the virus. Passaging does not change the characteristics of a virus, but is simply a process of growing more of the virus. Each time a viral particle is plaque purified or grown through passaging, it is identified with a new, sequential passage number. Professor Mayr plaque purified and/or passaged the MVA virus to passage 572. Upon reaching MVA 572, the MVA virus was genetically stable.

11. In the early 1970s, Professor Mayr transferred the MVA virus to a state institution of the Federal Republic of Germany where it was used to vaccinate 120,000 Germans against smallpox. No instances of injury or death were reported from those vaccinations, even for those with compromised immune systems. In fact, despite years of research and publications on the use of MVA, there do not appear to be any reports of MVA being unsafe for use with humans as a smallpox vaccine or viral vector.

12. Professor Mayr has grown additional MVA through additional passages of MVA 572 (*e.g.*, passages 574 and 575) and has made passages, including passages 572 and 575, publicly available to other persons and companies around the world. All MVA passages used in modern MVA smallpox vaccines, including those produced by Acambis and BN discussed below, trace their origin to MVA 572, the passage that Professor Mayr plaque-purified over 35 years ago to a genetically stable virus and used as the basis for a safe smallpox vaccine. Not

surprisingly, all MVA passages plaque purified from the original MVA 572 that are known to have been sequenced have the identical genetic sequence, even those that are many passage numbers removed from MVA 572. As a result, all such passages display the same “phenotypic,” *i.e.*, behavioral, characteristics.

13. Acambis’ MVA-based smallpox vaccine, MVA3000 (also known as “ACAM3000”), is intended to be used to vaccinate individuals, including children, the elderly, and immune-compromised persons, against smallpox. As set forth below, MVA3000 has been imported as a smallpox vaccine for the U.S. Government pursuant to U.S. Government contracts. Acambis obtained the MVA passage used as the basis for MVA3000 from the laboratories of Dr. Bernard Moss at the National Institutes of Health (“NIH”). Dr. Moss received the passage, MVA 572, from Professor Mayr. Dr. Moss plaque purified the MVA 572 received from Prof. Mayr several times before providing it to Acambis and others.

14. BN also produces an MVA-based smallpox vaccine, IMVAMUNE™, which is allegedly based on a viral strain that BN calls MVA-BN.

**REDACTED**

The first “F6” strain corresponded to passage number MVA F6 580, which was created by Gerd Sutter, a doctoral student working under Professor Mayr. Gerd Sutter brought MVA F6 580 to a public German institute, Forschungszentrum für Gesundheit (“GSF”), where another graduate student passaged it to MVA F6 582.

**REDACTED**

## **REDACTED**

### **U.S. Government RFPs for MVA-based Smallpox Vaccines**

15. After September 11, 2001, concerns that the smallpox virus may be used as a weapon by terrorists prompted new programs and funding to stockpile a smallpox vaccine. One such program involved a series of three U.S. Government Requests for Proposals (“RFP”) for MVA-based smallpox vaccines.

16. The first of the three MVA-RFPs, No. NIH-NIAID-DMID-03-44 (“RFP-1”), was directed to the research and development of an MVA smallpox vaccine demonstrating a “lack of or limited replication in animals.” That contract award was granted on February 14, 2003. The entire contract award of approximately \$15 million USD was divided between BN and Acambis.

17. The second in the series of MVA-based vaccine RFPs issued by the U.S. Government, No. NIH-NIAID-DMID-04-49 (“RFP-2”), was directed to the continued research and development of a MVA smallpox vaccine, including the manufacture of 500,000 doses of the MVA smallpox vaccine. RFP-2 required “evidence at the time of proposal submission that the offeror has secured access to [] intellectual property, know-how and tangible materials” necessary to fulfill the offeror’s obligations under the contract. The Government awarded that contract on September 30, 2004. Again, the contract award was split between BN and Acambis.

18. The third of the RFP series, No. DHHS-ORDC-V&B-05-06 (“RFP-3”), involves continued clinical testing and the manufacture and delivery of 10-20 million doses of the MVA smallpox vaccine. RFP-3 also includes the option for purchase of 60 million additional doses of the MVA smallpox vaccine and “warm-base” manufacturing over the longer term. “Warm-base” refers to keeping a manufacturing facility “warm” by producing a minimum amount of vaccine

each year for the U.S. Government. RFP-3 is by far the largest contract in terms of doses and may be worth up to approximately \$1 billion USD.

19. RFP-3 issued on August 15, 2005, and responses were due September 29, 2005. As originally issued, RFP-3 required that the bids include “documentation demonstrating unencumbered access” to all “intellectual property, know-how and tangible materials” necessary to fulfill the offeror’s obligations under the contract. This requirement was removed from RFP-3 just prior to submission of initial proposals.

20. Both Bavarian Nordic and Acambis have submitted bids for RFP-3. RFP-3 has not yet been awarded.

#### **BN’s MVA Patents**

21. BN is the assignee of all rights, title, and interest to U.S. Patent No. 6,761,893 (“the ‘893 patent”) issued on July 13, 2004, and U.S. Patent No. 6,913,752 (“the ‘752 patent”) issued on July 5, 2005. Both patents name Paul Chaplin, Paul Howley, and Christine Meisinger, all current or former BN employees, as the sole inventors. Paul Chaplin was at the time of the patent applications, and continues to serve as, BN’s Chief Scientific Officer.

22. Both the abstract and specification of the ‘893 and ‘752 patents are nearly identical. Both patents purport to recite a new MVA strain characterized by the alleged loss of capability to replicate in human cell lines, notably HaCat cells. The ‘893 patent claims the MVA virus that was purportedly deposited by BN with the European Collection of Cell Cultures (“ECACC”) and certain “derivatives thereof.”

**REDACTED**

The ‘752 patent claims MVA viruses that do not replicate in human cell lines that allow replication of a prior art passage, MVA 575.

**Invalidity of BN's MVA Patents**

23. The claims of the '893 and '752 patents are invalid on a number of grounds, including but not limited to anticipation, obviousness, improper inventorship, lack of enablement, and inadequate written description. The primary and only independent claims in the patents are clearly invalid as anticipated and for improper inventorship. Many of the dependent claims are also invalid on those bases; those that are not invalid on those grounds are invalid on other bases, such as obviousness.

24. With respect to anticipation, the primary and only independent claims in the patents are invalid both in the traditional sense and on the basis of inherent anticipation. While the patents purport to claim rights to certain MVA strains, all plaque purified MVA strains post-passage 572 are the same – upon information and belief, they all share the same genetic sequence and biological characteristics. Hence, because MVA-BN originated with MVA 572, it is anticipated by MVA-572 and its progeny.

**REDACTED**

25. The primary and only independent claims of the patents-in-suit are also inherently anticipated by prior art because any strains claimed thereby would have been necessarily present in the prior art. In fact, the patent itself states that the claimed virus was obtained through the process of plaque purification, whereby a viral particle is selected from a *pre-existing* virus. Hence, if arguably not identical to prior art viral strains such as MVA 572 and F6, MVA-BN *must* have existed within those strains and is thus inherently anticipated.

26. The PTO examiner suspected that BN's claims were likely anticipated by prior art MVA strains, but did not have the wherewithal to prove it. Instead, as noted in the prosecution history, she left it to BN's "rivals" to disprove BN's claims:

MVA stocks are in wide distribution and are maintained in many laboratories. If variants with one or more of the recited characteristics are common in randomly chosen plaques, then some other laboratory's stock of MVA probably inherently possesses one or more of the characteristics recited in the claim. The examiner does not have access to all stocks of MVA in public use, or facilities to test all existing stocks for the recited characteristics, and cannot meet the burden required to make an inherency rejection. However, applicant's rivals may be able to show inherent anticipation and invalidate broad patent claims, if in fact the recited characteristics are commonly found in random MVA isolates.

**REDACTED**

27. In addition to anticipation, both patents are invalid in their entirety for failing to name the proper inventors.

**REDACTED**

Indeed, the very vial on deposit at the ECACC that purportedly contains the patented virus is labeled "MVA F6."

**REDACTED**

;

**REDACTED**

Again, the examiner was not aware of this fundamental flaw in the patents because, as discussed below, BN, the named inventors, and/or their attorneys knowingly misrepresented such information in prosecuting the patents.

**Unenforceability of BN's MVA Patents**

28. In addition to being invalid, the '893 and '752 patents are unenforceable as BN, the named inventors, and/or their attorneys undertook a number of fraudulent and deceitful acts in order to obtain the referenced patents and exclude others from any rights thereto.

29. For example, BN, the named inventors, and/or their attorneys knowingly and affirmatively:

**REDACTED**

(2) misrepresented to the PTO examiner the nature and character of prior art strains in order to distinguish the claimed strain from prior art;

**REDACTED**

(4) withheld data directly contradicting affirmative representations made to the PTO examiner in order to distinguish prior art.

30. All of the material misrepresentations were carried out with the specific intent to defraud the PTO examiner in order to obtain the MVA-based patents. For example, as demonstrated by misrepresentations in the patents and prosecution histories, a primary goal of the fraudulent conduct was to hide prior art MVA F6 from the examiner so that the examiner would not know that the patented strain is nothing more than MVA F6. In fact, unbeknownst to the examiner, the very vial on deposit at the ECACC purportedly containing the patented virus is labeled "MVA F6."

**REDACTED**

31. The affirmative misrepresentations and intentionally withheld information were material to the issuance of the '893 and '752 patents. As explained above, the examiner doubted the claims of the patent, but did not have the resources to disprove those claims.

**REDACTED**

32. Following are a few specific examples of fraudulent misrepresentations made by BN, the named inventors, and/or their attorneys.

33.

**REDACTED**

For instance, both the '893 and '752 patents state that "the inventors identified and isolated in several rounds of clone purification a strain of the present invention starting with...MVA 575."

**REDACTED**



**REDACTED**

34. Second, BN, the named inventors and/or their attorneys made false statements regarding prior art, including MVA F6, in order to distinguish that art from the claimed strain. For instance, in Petitions to Make Special submitted in order to expedite review of the applications that gave rise to the '752 and '893, BN, the named inventors and/or their attorneys misrepresented that "[s]train F6 in Sutter, et al. basically corresponds to strain MVA 572 and 575 referenced in the present application." That statement is demonstrably false as BN, the named inventors, and/or their attorneys knew that F6 was plaque purified after MVA 572 and 575 and the immediate precursor to the claimed strain. While all MVA passages following MVA 572 have the same genotype and phenotype, to the extent that BN asserts that its purported strain is different, the patentees should have fully disclosed prior art MVA F6, the immediate precursor to MVA-BN.

**REDACTED**

35. Similarly, BN, the named inventors and/or their attorneys again sought to hide MVA F6 580 from the examiner in the Petitions to Make Special by asserting that a prior art article by Meyer *et al.* disclosed MVA 574, when in fact the article disclosed F6. The patentees stated that "the only difference between MVA 574 [allegedly disclosed in Meyer *et al.*] and MVA 572 is that MVA 574 has been passaged 574 times in CEF cells, where as MVA 572 has been passaged 572 times...." The applicants further represented that they had "established that MVA 572 and 575, and consequently MVA 574, do not exhibit the critical biological activity of

the viruses of Claim 1....”

**REDACTED**

36. Third, BN, the named inventors, and/or their attorneys misrepresented the nature and character of the viral strains evaluated in the *single* experiment that forms the basis for the patents-in-suit in order to distinguish the claimed strain from the prior art.

37. For instance, the experiment purports to compare the replication characteristics of MVA-BN to three other “known MVA strains”: (i) MVA-HLR, (ii) MVA Vero, and (iii) MVA-575. However, the prior art referred to as “MVA-HLR” was not a true or classical MVA virus, and the “MVA Vero” comparator had been grown in green monkey cells (whereas the patent teaches growth in CEF cells), which would have changed the characteristics of that virus and made it more likely to replicate.

38. Further, contrary to representations in the patents, the replication results for the last comparator strain, identified as “MVA 575,” showed no replication.

**REDACTED**

39.

**REDACTED**

Hence, the examiner could not have

known whether the patented strain as deposited has the same characteristics represented by the results of the single experiment set forth in the patent.

40. Fourth, upon information and belief, the following affirmative representations by BN, the named inventors, and/or their attorneys in the patents and/or Petitions to Make Special are false and were intended to distinguish the claimed strain from prior art:

## **REDACTED**

### **BN's Litigation Against Acambis**

41. BN is now asserting its clearly invalid and fraudulently obtained patents as a sword in litigation in an effort to prevent Acambis from competing in the MVA-based smallpox vaccine market and deter the U.S. Government from contracting with Acambis.

42. For example, on August 19, 2005, just four days after issuance of RFP-3 – which initially required bids to include “documentation demonstrating unencumbered access” to all “intellectual property, know-how and tangible materials” – BN filed a Complaint against Acambis with the United States International Trade Commission (“ITC”) alleging a violation of Section 337 of the Tariff Act of 1930 on the basis that the importation and sale of MVA3000 infringed the ‘893 and ‘752 patents and misappropriated BN’s alleged trade secrets and rights to alleged proprietary MVA strains (“ITC action”).

43. On September 19, 2005, in response to BN's complaint, the ITC instituted an Investigation based on the alleged patent infringement and trade secret misappropriation. Fact discovery in the ITC action was completed on February 20, 2006, and expert discovery was completed on March 10, 2006. On April 17, the Administrative Law Judge ("ALJ") summarily dismissed BN's trade secret misappropriation claim on the basis of a mandatory arbitration clause included in a non-disclosure agreement; the ALJ also summarily dismissed BN's alleged conversion claim on the basis that it was never part of the Investigation as instituted by the ITC. Those dismissals are now final.

44. A six-day evidentiary hearing before the ALJ on the patent infringement claims – the only claims remaining in the ITC action – began on May 8, 2006. Acambis has taken the position at trial that the patents-in-suit are invalid on a number of grounds, including anticipation by prior art MVA strains and inventorship errors, and that the patents are unenforceable due to BN's inequitable conduct before the PTO. Following post-trial briefing by the parties to that action, the ALJ is scheduled to issue an initial determination by August 24, 2006. The ITC is scheduled to issue a final determination in that action by November 24, 2006.

45. In addition, four days after the issuance of RFP-3 and simultaneous to the filing of the ITC action, BN brought the above-captioned action against Acambis in this Court on August 19, 2005. The Complaint as filed alleges claims for tortious conversion, misappropriation of trade secrets, violations of Delaware unfair competition laws and the Lanham Act.

46. BN's tortious conversion claim in this case is based on the allegation that BN "has a valid, property interest in MVA-572 and its progeny based on its exclusive license from Professor Mayr for the commercialization of all MVA strains." Complaint ¶ 46. BN claims that Acambis violated that property right by "possess[ing] MVA-572 and/or its progeny received

from” NIH. *Id.* ¶ 47. BN has further represented to the NIH that Acambis is an illegitimate participant in the RFP process on the basis that MVA3000 is based on a virus allegedly originating from a BN proprietary strain. NIH has rejected BN’s arguments and, upon information and belief, BN has no “property” interest in the MVA 572 passage provided to NIH and was fully aware of that fact prior to filing suit.

47. BN’s trade secrets claim is subject to a mandatory arbitration provision and should be dismissed from this action.

48. BN’s Delaware deceptive trade practices and unfair competition claims, and its Lanham Act claim, are rooted in BN’s trade secret and tortious conversion claims discussed above. Those claims assert that Acambis has engaged in false, deceptive, and unfair practices by “passing off” MVA3000 as a product of Acambis’ own research and property when, according to BN, MVA3000 is based on misappropriated trade secrets and tortiously converted property in the form of the MVA 572 received from NIH.

49. While the Complaint does not include patent infringement allegations, it specifically alleges, *inter alia*, that Acambis “has made false and/or misleading statements to customers and potential customers regarding Acambis’ freedom to operate within the field of MVA-based smallpox vaccines.” *See* Complaint ¶ 20. Several paragraphs prior, the Complaint references the ‘893 and ‘752 patents “directed to MVA-based vaccines.” *Id.* ¶ 14. Hence, it appears that the Lanham Act and Delaware deceptive practices and unfair competition claims may be based, at least in part, on such alleged “false and/or misleading statements.” *See id.* ¶¶ 63, 68.

**FIRST COUNTERCLAIM**  
**(Declaratory Judgment, Patent Invalidity)**

50. Acambis hereby incorporates and repeats each and every paragraph above as if set forth here in full.

51. Through its litigation against Acambis based on the '893 and '752 patents, BN has created a real, substantial and justiciable controversy between the parties.

52. The '893 and '752 patents are invalid for failure to comply with requirements for patentability including, but not limited to, those set forth in 35 U.S.C. §§ 101, 102, 103, and 112.

53. Acambis is therefore entitled to a judicial declaration that the '893 and '752 patents are invalid and an order permanently enjoining BN from, among other things, asserting or threatening to assert infringement of those patents against Acambis.

**SECOND COUNTERCLAIM**  
**(Declaratory Judgment, Patent Unenforceability)**

54. Acambis hereby incorporates and repeats each and every paragraph above as if set forth here in full.

55. Through its litigation against Acambis based on the '893 and '752 patents, BN has created a real, substantial and justiciable controversy between the parties.

56. BN, the named inventors, and/or their attorneys breached their duty of candor to the PTO by making affirmative misrepresentations of material facts, failing to disclose material information, and submitting false information to the PTO with the intent to deceive the PTO as set forth above.

57. The misrepresentations and withheld information were material to the issuance of the '893 and '752 patents.

58. The '893 and '752 patents were procured by inequitable conduct and by fraud and therefore are unenforceable.

59. Acambis is therefore entitled to a judicial declaration that the '893 and '752 patents are unenforceable and an order permanently enjoining BN from, among other things, asserting or threatening to assert infringement of those patents against Acambis.

**THIRD COUNTERCLAIM**  
**(Walker Process Fraud Sherman Act Violation, 15 U.S.C. § 2)**

60. Acambis hereby incorporates and repeats each and every paragraph above as if set forth here in full.

61. The United States market for MVA-based smallpox vaccines is a relevant market for antitrust purposes. That market is defined by the U.S. Government RFPs described above and the U.S. Government is the only present customer in the relevant market. As set forth above, the U.S. Government has issued several RFPs specifically directed at MVA-based smallpox vaccines. Hence, non-MVA based smallpox vaccines, such as those based on Dryvax®, are not substitutes for an MVA-based smallpox vaccine.

62. Barriers to entry in the defined market are high. Upon information and belief, BN has asserted that it is the only company with freedom to operate to meet the terms of the U.S. Government's RFPs for MVA-based smallpox vaccines. For instance, on July 19, 2004, BN issued a public announcement to the Copenhagen Stock Exchange stating that, with the issuance of the '893 patent, "Bavarian Nordic are unique in their ability to affirmatively demonstrate their 'freedom to operate'" to meet RFP-2. In that same announcement, BN's President and CEO, Peter Wulff, stated that "with the issuance of this broad patent to the MVA-BN® virus and its like acting derivatives, it will be difficult for others to develop and produce a safe and effective MVA-based vaccine without a license under this patent." BN has further asserted that

MVA3000 infringes the '893 and '752 patents because it meets the requirements set forth in the U.S. Government RFPs.

63. As alleged above, the '893 and '752 patents were procured by inequitable conduct and by fraud and therefore are unenforceable. The PTO examiner relied on BN's intentionally false statements and/or deliberate omissions as the subject matter of the patents is not otherwise patentable. The patents would not have been granted but for BN's fraudulent conduct.

64. Through the use of the fraudulently obtained '893 and '752 patents, and with full knowledge of the fraudulent acts undertaken to secure such patents, BN is seeking to prohibit companies, such as Acambis, from competing in the relevant market so as to monopolize and/or attempt to monopolize interstate trade and commerce in that market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

65. BN has undertaken the anticompetitive acts alleged herein with the specific intent to eliminate Acambis and other competitors and potential competitors from trade and commerce in the MVA-based smallpox vaccine market by preventing all other competitors from bidding on, obtaining, and/or fulfilling contract awards for U.S. Government RFPs for MVA-based smallpox vaccines, and by deterring the U.S. Government from purchasing competitive products.

66. As a result of BN's acts, competition in the sale of MVA-based smallpox vaccines will be reduced. The reduction in competition from BN's acts will result in a reduction of MVA-based smallpox vaccine suppliers and higher prices for MVA-based smallpox vaccines.

67. Acambis has sustained antitrust injury and substantial damages to its business and property as a direct and proximate result of BN's anticompetitive conduct. Such injury and damages include, *inter alia*, the substantial amounts that Acambis has been forced to expend and is continuing to expend in order to compete in the MVA-based smallpox vaccine market by



defending against BN's fraudulently procured MVA-based patents before the ITC and in this Court; an artificial decrease in the value of Acambis stock; harm to Acambis' reputation and good will; and to the extent that BN's illegal scheme is successful, harm to Acambis' ability to compete for, obtain, and fulfill contracts offered by the U.S. Government.

68. Acambis seeks damages in an amount to be determined at trial, trebled, and attorneys' fees as provided by Section 4 of the Clayton Act, 15 U.S.C. § 15.

**FOURTH COUNTERCLAIM**  
**(Sham Litigation Sherman Act Violation, 15 U.S.C. § 2)**

69. Acambis hereby incorporates and repeats each and every paragraph above as if set forth here in full.

70. BN's litigation against Acambis as set forth above – based on patents that it knew were invalid and/or unenforceable and a meritless tortious conversion claim that asserts “exclusive” property rights in “MVA-572 and its progeny” – constitutes a sham in that such litigation is objectively baseless and brought with the subjective and specific intent of monopolizing the MVA-based smallpox vaccine market by preventing all other competitors from bidding on, obtaining, and/or fulfilling contract awards for U.S. Government RFPs for MVA-based smallpox vaccines, and by deterring the U.S. Government from purchasing competitive products.

71. BN has undertaken the anticompetitive acts alleged herein with the specific intent to eliminate Acambis and other competitors and potential competitors from trade and commerce in the MVA-based smallpox vaccine market.

72. As a result of BN's acts, competition in the sale of MVA-based smallpox vaccines will be reduced. The reduction in competition from BN's acts will result in a reduction of MVA-based smallpox vaccine suppliers and higher prices for MVA-based smallpox vaccines.

73. Acambis has sustained antitrust injury and substantial damages to its business and property as a direct and proximate result of BN's anticompetitive conduct. Such injury and damages include, *inter alia*, the substantial amounts that Acambis has been forced to expend and is continuing to expend in order to compete in the MVA-based smallpox vaccine market by defending against BN's sham litigation before the ITC and in this Court; an artificial decrease in the value of Acambis stock; harm to Acambis' reputation and good will; and to the extent that BN's illegal scheme is successful, harm to Acambis' ability to compete for, obtain, and fulfill contracts offered by the U.S. Government.

74. Acambis seeks damages in an amount to be determined at trial, trebled, and attorneys' fees as provided by Section 4 of the Clayton Act, 15 U.S.C. § 15.

**FIFTH COUNTERCLAIM**  
**(Tortious Interference with Contracts and Business Expectancies)**

75. Acambis hereby incorporates and repeats each and every paragraph above as if set forth here in full.

76. Acambis has valid contracts, business relations, and business expectancies relating to the production and sale of its MVA3000 vaccine to the U.S. Government.

77. BN knows that Acambis has valid contracts, business relations, and business expectancies with the U.S. Government relating to the production and sale of its MVA3000 vaccine to the U.S. Government.

78. BN, through the conduct alleged above, has sought to intentionally interfere with Acambis' valid contracts, business relations, and business expectancies in an illegal effort to prevent, limit, or increase the cost of Acambis' sale of MVA3000 vaccine to the U.S. Government.

79. BN's conduct lacks justification and was undertaken for malicious purposes and/or with reckless indifference to the rights of others.

80. As a direct and proximate cause of BN's conduct, Acambis has been injured and has sustained damages.

81. Acambis is entitled to actual and punitive damages.

**SIXTH COUNTERCLAIM**  
**(Lanham Act False Advertising, 15 U.S.C. § 1125(a))**

82. Acambis hereby incorporates and repeats each and every paragraph above as if set forth here in full.

83. In connection with its efforts to sell its MVA-BN vaccine, BN has falsely and/or misleadingly represented that Acambis' MVA3000 vaccine infringes BN's MVA-based patents and is based on a viral strain that Acambis has no right to possess, and that BN has the sole right to offer an MVA-based vaccine to the U.S. Government.

84. BN's false and misleading representations constitute commercial advertising and promotion of goods in interstate commerce.

85. BN's false and/or misleading representations constitute misrepresentations regarding the nature, characteristics, and qualities of the products at issue, are literally false, and are relied upon by consumers in making a purchasing decision.

86. The above acts constitute a violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

87. Acambis, a competitor of BN's in the sale of MVA-based smallpox vaccines, has been and is being irreparably injured by BN's illegal practices and has suffered monetary damages in an amount not yet ascertained. These injuries will continue to mount until the misrepresentations are enjoined.

88. Acambis is entitled to BN's profits, treble damages, and the costs of this action pursuant to 15 U.S.C. § 1117.

89. Acambis is entitled to an award of attorneys' fees as this is an exceptional case under 15 U.S.C. § 1117.

**SEVENTH COUNTERCLAIM**  
**(Delaware Deceptive and Unfair Trade Practices)**

90. Acambis hereby incorporates and repeats each and every paragraph above as if set forth here in full.

91. In the course of its business, BN has disparaged Acambis and its MVA3000 product by falsely and/or misleadingly stating that MVA3000 infringes BN's MVA-based patents and is based on a viral strain that Acambis has no right to possess.

92. BN has also falsely represented that it has the sole right to offer an MVA-based vaccine to the U.S. Government.

93. The above acts constitute false and/or misleading representations of fact in violation of the Delaware Deceptive Trade Practices Act, Del. Code Ann. Tit. 6 § 2531 *et seq.*, and Delaware common law of unfair competition.

94. Acambis, a competitor of BN's in the sale of MVA-based smallpox vaccines, has been and is being irreparably injured by BN's illegal practices and has suffered monetary damages in an amount not yet ascertained. These injuries will continue to mount until the misrepresentations are enjoined.

95. Acambis is entitled to damages, the costs of this action, and attorneys' fees as this is an "exceptional" case and BN willfully engaged in the illegal practices described above.

**PRAYER FOR RELIEF**

WHEREFORE Acambis respectfully demands that the Court enter judgment against counterclaim Defendant BN and in favor of counterclaim Plaintiff Acambis along with the following relief:

1. A judicial declaration that the '893 and '752 patents are invalid and unenforceable and an order permanently enjoining BN from, among other things, asserting or threatening to assert infringement of those patents against Acambis;

2. Awarding Acambis treble its actual damages arising from BN's anticompetitive conduct, plus Acambis' costs of this suit and reasonable attorneys' fees, pursuant to Section 4 of the Clayton Act, 15 U.S.C. § 15;

3. Awarding Acambis actual and punitive damages arising from BN's tortious interference with Acambis' valid contracts, business relations, and/or business expectancies;

4. Awarding Acambis an accounting of BN's profits that BN has received through its false and/or deceptive acts and practices, treble actual damages, costs, and attorneys' fees based on BN's false advertising under the Lanham Act, 15 U.S.C. § 1117, and enjoining BN from the false and/misleading statements described herein;

5. Awarding Acambis damages, the costs of this action, and attorneys' fees under Delaware Deceptive Trade Practices Act, Del. Code Ann. Tit. 6 § 2531 *et seq.* and Delaware common law of unfair competition and enjoining BN from the false and/or misleading statements described herein.

**DEMAND FOR A JURY TRIAL**

Defendants respectfully demand a trial by jury on all issues, claims, and causes of action appropriately tried to a jury.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ James W. Parrett, Jr. (#4292)*

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